9. [AMENDED] The pharmaceutical composition of claim 1 wherein said antibody comprises a light chain CDR1 region having the amino acid sequence of SEQ ID NO:11.

10. [AMENDED] The pharmaceutical composition of claim 1 wherein said antibody comprises a light chain region having the amino acid sequence of SEQ ID NO:9.

14. [AMENDED] A method for the treatment of active RSV disease comprising administering to a patient in need of such treatment a therapeutically effective amount of a pharmaceutical composition of claim 1.

15. [AMENDED] A method for prophylactic treatment against infection by RSV comprising administering to a patient in need of such treatment a prophylactically effective amount of a pharmaceutical composition of claim 1.

Please add claims 18 and 19, as follow.

--18. A method for the treatment of active RSV disease comprising administering to a patient in need of such treatment a therapeutically effective amount of a pharmaceutical composition of claim 1.--

--19. A method for prophylactic treatment against infection by RSV comprising administering to a patient in need of such treatment a prophylactically effective amount of a pharmaceutical composition of claim 1.--

REMARKS

Claims 1-10 and 13-19 are pending. Claims 1-10, 14 and 15 are amended to clarify the subject matter sought to be patented. Claims 11 and 12 are canceled without

prejudice or disclaimer. Claims 18 and 19 are added. Claim 13 is withdrawn. No new matter has been added.

Attached hereto is a marked-up version of the changes made to the specification and/or claims by the current amendment. The attached page is captioned "Version With Markings To Show Changes Made."

The Office Action broadly objects to, and has not entered, the amendments to the specification set forth in the Submission of Sequence Listing filed November 14, 2000 (Paper 12). In the particular, the Office Action states that amendments were not entered because the line numbers recited in the amendment do not correspond to the specification. On the contrary, Applicant respectfully disagree. In the next Office communication, clarification is respectfully requested on the specific amendments that are being objected to by the Office Action.

The Office Action broadly objects to the specification because it allegedly contains sequence that are not labeled with a SEQ ID NO. Applicants respectfully disagree. In the next Office communication, Applicants respectfully request clarification by page and line number as to where the allegedly non-labeled sequences are located because it is believed that the amendments filed on November 14, 2000 (Paper 12), would overcome this objection, if entered. 1.821 d

The Office Action provisionally rejects claims 1-12, 14 and 15 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of co-pending Application No. 09/043,522. In response, Applicants respectfully acknowledge the need to cancel claims or to file a Terminal Disclaimer if ultimately allowed claims in the above-captioned patent application improperly conflict

with, or extend the patent right in, the copending patent application. Applicants respectfully request that this rejection be held in abeyance until allowable subject matter is indicated.

The Office Action rejects claim 14 under 35 U.S.C. 112, first paragraph, allegedly because the specification does not enable any person skilled in the art to make and use the invention commensurate in scope with the claims. In particular the Office Action asserts that the specification does not reasonably provide enablement for the use of all antibodies with specificity for a RSV F glycoprotein epitope for the therapeutic treatment of RSV infections. In response, solely in an effort to advance prosecution, Applicants have amended claim 14 to overcome this rejection. Thus, Applicants respectfully request reconsideration and withdrawal of the rejection of claim 14.

The Office Action rejects claim 15 under 35 U.S.C. 112, first paragraph, allegedly because the specification does not enable any person skilled in the art to make and use the invention commensurate in scope with the claims. In particular, the Office Action asserts that the specification does not provide enablement for the prophylactic treatment (prevention) of RSV infection. Applicants respectfully traverse this rejection.

The Examiner is required to present evidence of inoperability. *See In re Gazave*, 379 F.2d 973, 154 U.S.P.Q. 92 (C.C.P.A. 1967)). Moreover, the Federal Circuit has held that a patent need not teach, and preferably omits, what is well known in the art. *See In re Buchner*, 18 U.S.P.Q.2d 1331 (Fed. Cir. 1991). The test for enablement is whether one of ordinary skill in the art can make or use the claimed invention without undue experimentation in light of the application disclosure coupled with the information known in the art. *United States v. Telectronics, Inc.*, 8 U.S.P.Q.2d 1217 (Fed. Cir. 1988). In

describing the claimed invention, the Applicants are not required to explain every detail since they are speaking to those of ordinary skill in the art. *In re Howarth*, 210 U.S.P.Q. 690, 691 (CCPA 1981). Thus, a patent may be enabling even though some experimentation is necessary, as long as the amount of the experimentation is not unduly extensive. *Utter v. Hiraga*, 6 U.S.P.Q.2d 1709, 1714 (Fed. Cir. 1988).

Further, there is no magical relationship between the number of representative examples and the breadth of the claims. In fact, no working examples are necessary. *In re Borkowski*, 164 U.S.P.Q. 642 (CCPA 1970). When a term is supported by the specification, Applicants should not be denied the use of the term merely because it is broad. *In re Grier*, 144 U.S.P.Q. 654 (CCPA 1965). As explained by the Court of Customs and Patent Appeals:

> Appellants have apparently not disclosed every catalyst which will work; they have apparently not disclosed every catalyst which will not work. The question, then, is whether in an unpredictable art, section 112 requires disclosure of a test with every species covered by a claim. To require such a complete disclosure would apparently necessitate a patent application or applications with "thousands" of examples or the disclosure of "thousands" of catalysts along with information as to whether each exhibits catalytic behavior resulting in the production of hydroperoxides. More importantly, such a requirement would force an inventor seeking adequate patent protection to carry out a prohibitive number of actual experiments. This would tend to discourage inventors from filing patent applications in an unpredictable area since the patent claims would have to be limited to those embodiments which are expressly disclosed.

In re Angstadt, 190 U.S.P.Q. 214, 218 (CCPA 1976). In line with this statement, the Court of Customs and Patent Appeals in *In re Johnson and Farnham*, 194 U.S.P.Q. 187, 195 (CCPA 1977), citing *In re Goffe*, 191 U.S.P.Q. 429, 431 (CCPA 1976), exemplified:

> [T]o provide effective incentives, claims must adequately protect inventors. To demand that the first to disclose shall limit his claims to what he has found will work or to materials which meet the guidelines specified for "preferred" materials in a process such as the one herein involved would not serve the constitutional purpose of promoting progress in the useful arts.

Applicants respectfully point out that the specification at pages 25-26 adequately states that the disclosed monoclonal antibodies may be used immunotherapeutically to provide a prophylactic or therapeutic composition against RSV infection. Such applications/uses for the disclosed monoclonal antibodies would readily be appreciated by those skilled in the art. The present specification is not a "hunting license", as inferred by the Office Action. The specification contains a adequate guidance on how to use the pharmaceutical compositions/preparations.. *In re Brana*, 51 F.2d 1560, 1566, 34 U.S.P.Q.2d 1437, 1441 (Fed. Cir. 1993). *In re Johnson*, 282 F.2d 370, 373, 127 U.S.P.Q. 216, 219 (C.C.P.A. 1960); and *In re Hitchings*, 342 F.2d 80, 87, 144 U.S.P.Q. 637, 643 (C.C.P.A. 1965). Evidence of efficacy, safety, toxicity, routes of administration and dosage of the recited compounds are not required to be disclosed because such issues are readily determinable in the art via **routine** (even if possibly extensive) experimentation. Indeed, such evidence is addressed and reviewed by other governmental regulations and agencies. In short, Applicants provide specific and useful teachings with enough detail to enable one skilled in the art to make and used the claimed invention. Thus, Applicants respectfully request reconsideration and withdrawal of the rejection of claim 15 under 35 U.S.C. § 112, first paragraph.

The Office Action rejects claims 1-12, 14 and 15 under 35 U.S.C. 112, second paragraph, for allegedly failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

In particular, the Office Action asserts that claim 1 is vague and indefinite because it is not clear what degree of purity must be achieved for a given preparation to be considered "substantially pure." In response, Applicants respectfully submit that claim 1 does not require the **preparation** to be substantially pure, but rather that the recited **antibody**. Moreover, the specification beginning at page 8, line 26, adequately defines the meaning of the term "substantially pure." Thus, reconsideration and withdrawal of this aspect of the rejection under 35 U.S.C. 112, second paragraph are respectfully requested.

In addition, the Office Action further asserts that claims 11 and 12 are dependent claims that do not further limit the scope of claim 1. Applicants respectfully disagree. However, solely in a effort to advance prosecution, Applicants have canceled claims 11 and 12 without prejudice or disclaimer of its subject matter. This aspect of the rejection under 35 U.S.C. 112, second paragraph is rendered moot.

The Office Action rejects claims 1-12 and 14-15 under 35 U.S.C. 103(a) as being obvious over WO 92/04381 ("Harris"). The Office Action states that Harris "does not specifically recite the amino acid sequences of the neutralizing epitopes and/or CDR regions of the neutralizing antibodies...one would conclude that neutralizing antibodies with a specificity for the same protein would contain the same CDRs and with the same amino acide sequence." Applicants respectfully traverse this rejection.

The initial burden of establishing a ***prima facie*** basis to deny patentability to a claimed invention under any statutory provision always rests on the PTO. *In re Mayne*,

104 F.3d 1339, 41 U.S.P.Q.2d 1451 (Fed. Cir. 1997); *In re Oetiker,* 977 F. 2d 1443, 24 U.S.P.Q.2d 1443 (Fed. Cir. 1992). Applicants respectfully submit that the Office Action has not discharged this initial burden. An analysis of obviousness must be based on several factual inquiries: (1) the scope and content of the prior art; (2) the differences between the prior art and the claims at issue; (3) the level of ordinary skill in the art at the time the invention was made and (4) objective evidence of nonobviousness, if any. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18, 148 U.S.P.Q. 459, 467 (1966). A claim must be considered as a whole when being analyzed for obviousness, but differences between the claim and the prior art must be identified so that the obviousness analysis is placed in the proper perspective. In order for any invention to be obviated, the prior art must suggest the desirability of making the claimed invention. The prior art items themselves must suggest the desirability and thus the obviousness of the claimed invention without the slightest recourse to the teachings of the patent or application. Without such independent suggestion, the prior art is to be considered merely to be inviting experimentation, which is not the standard with which obviousness is determined. *In re Laskowski*, 871 F.2d 115, 117, 10 U.S.P.Q.2d 1397, 1398 (Fed. Cir. 1989); *In re Dow Chemical Co.*, 837 F.2d 469, 473, 5 U.S.P.Q.2d 1529, 1532 (Fed. Cir. 1988); *Hodosh v. Block Drug Co., Inc.*, 786 F.2d 1136, 1143 n. 5, 229 U.S.P.Q. 182, 187 n. 5 (Fed. Cir. 1986); *In re Gordon*, 733 F.2d 900, 902, 221 U.S.P.Q. 1125, 1127 (Fed. Cir. 1985); *In re Regel*, 526 F.2d 1399, 1403 n. 6, 188 U.S.P.Q. 136, 139 n. 6 (C.C.P.A. 1975).

Applicants respectfully submit that the Office Action has used the rejected claims as a blueprint with the deficient Harris reference by making mere conclusory assertions,

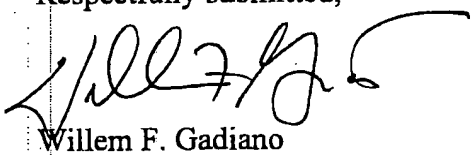
which are not 'evidence.'" *In re Dembiczak*, 175 F.3d 994, 999, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999). The Office Action provides no support for its broad conclusory statement that the subject matter of the rejected claims was known in, or reasonably expected from, the cited prior art. Nor does the Office Action provide support for its implicit finding that the claimed invention would have been obvious to one of ordinary skill in the art reading Harris. In fact, nowhere does the Office Action particularly identify any suggestion, teaching, or motivation in Harris, let alone any cogent technical reasoning, that would have guided one of ordinary skill in the art to achieve the claimed invention. As acknowledged by the Office Action, Harris merely discloses altered and humanized mouse antibodies reactive with certain epitopes on the F protein. Those of ordinary skill in the art reading Harris would have expected the disclosed altered humanized mouse antibodies to be susceptible to HAMMA (human anti-mouse MAb) response. *See* the specification at page 4, line 17. Harris simply does not disclose, suggest, or provide any motivation to one of ordinary skill in the art to make or use a fully human antibody having a CDR3 region comprising the amino acid sequence of SEQ ID NO. 7 (which is reactive to aa residue number 429 of the RSV F glycoprotein), as required by the claimed invention. Applicants respectfully submit that the absence of a convincing discussion of the specific sources of any motivation, suggestion or expectation of success to reach the claimed invention in the cited Harris reference is a critical omission in the pending obviousness rejection. Thus, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. 103.

Early consideration and prompt allowance of the pending claims are respectfully requested. If anything could be done to place this application in condition for allowance,

e.g., by Examiner's Amendment, Applicants respectfully request that the Examiner contact the undersigned representative at the telephone number listed below.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees, including extension of time fees, to Deposit Account 50-0417 and please credit any excess fees to such deposit account.

Respectfully submitted,



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ATTACHMENT

"Version With Markings To Show Changes Made."

1. [AMENDED] A pharmaceutical ~~preparation~~ composition comprising:

a pharmaceutically acceptable carrier; and

a substantially pure antibody binding an RSV F glycoprotein epitope, wherein said antibody ~~includes~~ comprises a heavy chain CDR3 region having the amino acid sequence of SEQ ID NO:7.

2. [AMENDED] The pharmaceutical ~~preparation~~ composition of claim 1 wherein said antibody comprises an Fd fragment.

3. [AMENDED] The pharmaceutical ~~preparation~~ composition of claim 1 wherein said antibody comprises an Fab fragment.

4. [AMENDED] The pharmaceutical ~~preparation~~ composition of claim 1 wherein said antibody includes a heavy chain CDR2 region ~~having~~ comprising the amino acid sequence of SEQ ID NO:5.

5. [AMENDED] The pharmaceutical ~~preparation~~ composition of claim 1 wherein said antibody comprises ~~includes~~ a heavy chain CDR1 region having the amino acid sequence of SEQ ID NO:3.

6. [AMENDED] The pharmaceutical ~~preparation~~ composition of claim 1 wherein said antibody ~~includes~~ comprises a heavy chain Fd region having the amino acid sequence of SEQ ID NO:1.

7. [AMENDED] The pharmaceutical ~~preparation~~ composition of claim 1 wherein said antibody ~~includes~~ comprises a light chain CDR3 region having the amino acid sequence of SEQ ID NO:15.

8. [AMENDED] The pharmaceutical ~~preparation~~ composition of claim 1 wherein said antibody ~~includes~~ comprises a light chain CDR2 region having the amino acid sequence of SEQ ID NO:13.

9. [AMENDED] The pharmaceutical ~~preparation~~ composition of claim 1 wherein said antibody ~~includes~~ comprises a light chain CDR1 region having the amino acid sequence of SEQ ID NO:11.

ATTACHMENT

"Version With Markings To Show Changes Made."

10. [AMENDED] The pharmaceutical ~~preparation~~ composition of claim 1 wherein said antibody ~~includes~~ comprises a light chain region having the amino acid sequence of SEQ ID NO:9.

11. [CANCELED]

12. [CANCELED]

13. [WITHDRAWN]

14. [AMENDED] A method for the treatment of active RSV disease comprising administering to a patient in need of such treatment a therapeutically effective amount of a pharmaceutical composition of claim 1 ~~, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11 or 12~~.

15. [AMENDED] A method for prophylactic treatment against infection by RSV comprising administering to a patient in need of such treatment a ~~therapeutically~~ prophylactically effective amount of a pharmaceutical composition of claim 1 ~~, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11 or 12~~.

18. [NEW] A method for the treatment of active RSV disease comprising administering to a patient in need of such treatment a therapeutically effective amount of a pharmaceutical composition of claim 1.

19. [NEW] A method for prophylactic treatment against infection by RSV comprising administering to a patient in need of such treatment a prophylactically effective amount of a pharmaceutical composition of claim 1.